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| Substitute for form 1449/PTO  |   | <b>Complete if Known</b> |                        |          |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br>(Use as many sheets as necessary) |   | Application Number       | 10/797,374             |          |
|   |   | Filing Date              | 2004-3-10              |          |
|   |   | First Named Inventor     | Phillips, Jeffery O    |          |
|   |   | Art Unit                 | 1625                   |          |
|   |   | Examiner Name            | Chang, Celia C.        |          |
| Sheet   | 1 | 6                        | Attorney Docket Number | 04242350 |

| U.S. PATENT DOCUMENTS |                       |  |                           |  |   |
|-----------------------|-----------------------|--|---------------------------|--|---|
| Examiner<br>Initials* | Cite No. <sup>1</sup> | Document Number                          | Issued Date<br>YYYY-MM-DD | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or<br>Relevant Figures Appear |
|                       |                       | Number-Kind Code <sup>2</sup> (if known) |                           |  |   |
|                       | A1                    | 5254682                                  | 1993-10-19                | Dhanoa, et al.                                     |   |

| NON-PATENT LITERATURE |                          |  |
|-----------------------|--------------------------|--|
| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. |
| /CC/                  | B1                       | ANSEL, et al., Pharmaceutical Dosage Forms and Drug Delivery Systems, p. 77, Williams & Wilkins, 6th ed. (1995)  |
|                       | B2                       | BADER, et al., "An Open Trial of Omeprazole in Short-Term Treatment of Duodenal Ulcer", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 177-178 (1986).   |
|                       | B3                       | BARON, et al., "Discussion", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, p. 117. (1986).  |
|                       | B4                       | BARON, et al., "Discussion", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, p. 122 (1986).   |
|                       | B5                       | BENDTSEN, et al., "Intraduodenal pH During Omeprazole Treatment in Duodenal Ulcer Patients", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 156-157 (1986).  |
|                       | B6                       | BERGLINDH, Thomas, "How to Study Properties of a Terminal Step Acid-Secretory Inhibitor <i>In Vitro</i> ", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 47-48 (1986).  |
|                       | B7                       | BERGLINDH, et al., "Discussion", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, p. 96-98 (1986).   |
|                       | B8                       | BLOM, Hakan, "Effects of Omeprazole on Normal and Regenerating Gastric Mucosa in the Rat. A Light and Electron Microscopic Study", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 70-71 (1986).  |
|                       | B9                       | BLUM, et al., "Discussion", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, p. 134-135(1986).   |
|                       | B10                      | BRANDSTROM, et al., "Structure-Activity Relationship of Substituted Benzimidazoles", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 54-56 (1986).  |
|                       | B11                      | BYROD, Eva, "Direction for Use of Omeprazole", pp. 1-3.  |
|                       | B12                      | CARLSSON, et al., "Pharmacology and Toxicology of Omeprazole with Special Reference to the Effects on Gastric Mucosa", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 31-38 (1986).  |
| /CC/                  | B13                      | COLIN-JONES, et al., "Discussion", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, p. 128 (1986).   |

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| /CCI/ | B14 | COLIN-JONES, et al., "Discussion", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 187-194 (1986).  |
|       | B15 | CREAN, et al., "Discussion", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, p. 46 (1986).  |
|       | B16 | DAMMAN, et al., "Intragastric Acidity Under a 28-Day Omeprazole Treatment", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 154-155 (1986).   |
|       | B17 | DARLE, et al., "Rate of Healing of Benign Gastric Ulcer During Treatment with Omeprazole", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, p. 180 (1986).   |
|       | B18 | DELCHIER, et al., "Long-Term Treatment with Omeprazole in Seven Patients with Zollinger-Ellison Syndrome Resistant to H <sub>2</sub> -Antagonists", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 184-186 (1986).         |
|       | B19 | DENT, et al., "Effects of Omeprazole on Peptic Oesophagitis and Oesophageal Motility and pH", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, p. 181 (1986).  |
|       | B20 | DIVE, et al., "Rate of Duodenal Ulcer Healing During Treatment with Omeprazole. A Double-Blind Comparison of a Daily Dose of 30 mg Versus 60 mg", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 175-176 (1986).           |
|       | B21 | EARNST, David, "Controlling Gastric pH: The Impact of Newer Agents on the Critically Ill Patient", DICP Ann. Pharmacother., Vol. 24 (Suppl.), pp. S31-S34 (1990).  |
|       | B22 | FESTEN, et al., "The Effect of Oral Omeprazole on Gastric Acid and Pepsin Secretion", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 158-159 (1986).   |
|       | B23 | FESTEN, et al., "Effect of Oral Omeprazole on Fasting and Meal Stimulated Serum Gastrin and Serum Pepsinogen I Levels in Healthy Volunteers", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 160-161 (1986).               |
|       | B24 | FIMMEL, et al., "The Effects of Omeprazole on Acid and Pepsin Secretion in the Isolated, In Vitro Perfused Whole Mouse Stomach", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 68-69 (1986).                              |
|       | B25 | FLEMSTROM, et al., "Effects of Omeprazole on Gastric and Duodenal Bicarbonate Secretion", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 65-67 (1986).   |
|       | B26 | FORSSELL, et al., "Structure and Function of the Dog Gastric Mucosa During and After a 1-Year Treatment with Omeprazole. I. Macro- and Microscopic Findings", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 79-81 (1986). |
|       | B27 | HAKANSON, et al., "Gastrin and the Trophic Control of Gastric Mucosa", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 18-30 (1986).  |
| /CCI/ | B28 | HANSSON, et al., "Toxicology Studies with Omeprazole", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 89-91 (1986).  |

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| /CC/ | B29 | HOWDEN, et al., "An Investigation into the Effects of Omeprazole on Renal Tubular Function and Endocrine Function in Man", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 169-170 (1986).  |
|      | B30 | HUTTEMANN, W., "Short-Term Treatment of Gastric Ulcer with Once Daily Omeprazole", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, p. 179 (1986).   |
|      | B31 | KITTANG, et al., "Effect of Omeprazole on the Secretion of Intrinsic Factor, Gastric Juice and Pepsin in Man", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 162-163 (1986).  |
|      | B32 | LAMERS, Cornelis, "Present Experiences with Omeprazole in the Zollinger-Ellison Syndrome", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 123-127 (1986).  |
|      | B33 | LARSEN, et al., "Effects of Omeprazole and Cimetidine on Mucosal Acid Secretion, Blood Flow and Oxygen Consumption in the Dog <i>Ex Vivo</i> Gastric Chamber", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 61-64 (1986).                    |
|      | B34 | LARSSON, et al., "Animal Pharmacodynamics of Omeprazole. A Survey of its Pharmacological Properties <i>in vivo</i> ", Scand. J. Gastroenterology, Vol. 20, Suppl. 108, pp. 23-35 (1985).   |
|      | B35 | LARSSON, et al., "Inhibition of Rat Gastric H <sup>+</sup> -K <sup>+</sup> -ATPase <i>In Vivo</i> . Relation to Reduction of Acid Secretion", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 57-58 (1986).                                     |
|      | B36 | LIND, et al., "Long-Term Acid Inhibitory Effect of Different Daily Doses of Omeprazole 24 Hours After Dosing", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 137-138 (1986).  |
|      | B37 | MARDH, Sven, "Omeprazole Inhibits the Formation of Acid in the Parietal Cell by a Direct Inhibition of the H <sup>+</sup> -K <sup>+</sup> -ATPase, the Acid Pump of the Stomach", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 49-51 (1986). |
|      | B38 | MATTSSON, et al., "Effect of Omeprazole on Gastric Mucosal Blood Flow in the Rat", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 72-74 (1986).  |
|      | B39 | MATTSSON, Hillevi, "Protective Effects of Omeprazole in the Gastric Mucosa", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 86-88 (1986).  |
|      | B40 | MCARTHUR, et al., "Omeprazole: An Effective Drug for Zollinger-Ellison Syndrome", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 182-183 (1986).   |
|      | B41 | MULLER, et al., "Acid Secretion During and After Omeprazole Treatment in Healthy Volunteers", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 141-142 (1986).   |
| /CC/ | B42 | NAESDAL, et al., "Diurnal Intragastric Acidity During Omeprazole Treatment in Patients with Peptic Ulcer Disease", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 150-151 (1986).  |

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| /CC/ | B43 | NIELSEN, et al., "Immediate Effect of Omeprazole and Cimetidine on Apparent Liver Blood Flow in Man", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 166-168 (1986).                                 |
|      | B44 | OKABE, et al., "Effects of Omeprazole on Gastric Secretion and Experimental Ulcers in Rats", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 75-76 (1986).  |
|      | B45 | OLBE, et al., "Effect of Omeprazole on Gastric Acid Secretion in Man", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 105-107 (1986).  |
|      | B46 | PECKMAN, "Alternative Method for Administering Proton-Pump Inhibitors Through Nasogastric Tubes", American Journal of Health-System Pharmacists, Vol. 56, p. 1020 (May 15, 1999).                          |
|      | B47 | POULSEN, et al., "Omeprazole Accelerates Healing of Cysteamine Induced Duodenal Ulcers in Rat", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 77-78 (1986).   |
|      | B48 | POUNDER, et al., "Twenty-Four Hour Intragastric Acidity during Treatment with Oral Omeprazole", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 108-116 (1986).                                       |
|      | B49 | Prilosec Production Information, Rev. 07/05, submitted with NDA 19-810.  |
|      | B50 | REGARDH, C.S., "Pharmacokinetics and Metabolism of Omeprazole in Man", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 99-104 (1986).   |
|      | B51 | ROHNER, et al., "Oral Omeprazole, 20 mg Versus 30 mg Once Daily: Effect on Healing Rates in 115 Duodenal Ulcer Patients", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 173-174 (1986).             |
|      | B52 | RYBERG, et al., "Gastric Acid Secretion and Plasma Gastrin Levels in Dogs Treated with High Oral Doses of Ranitidine and Omeprazole", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 94-95 (1986).   |
|      | B53 | SACHS, George, "The Parietal Cell as a Therapeutic Target", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 1-10 (1986).  |
|      | B54 | SACHS, et al., "Discussion", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, p. 17 (1986).  |
|      | B55 | SEWING, et al., "Effect of Substituted Benzimidazoles on H <sup>+</sup> -K <sup>+</sup> -ATPase of Isolated Guinea-pig Parietal Cells", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 52-53 (1986). |
|      | B56 | SHARMA, et al., "Acid Secretory Capacity After Treatment with Omeprazole", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 143-144 (1986).  |
| /CC/ | B57 | SHEARMAN, et al., "The Inhibition of Nocturnal Gastric Acid Secretion by Omeprazole in Patients with Duodenal Ulcer", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 145-146 (1986).                 |

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| /CCI/         | B58 | SHEARMAN, et al., "Effect of Omeprazole on Gastric Emptying in Patients with a History of Duodenal Ulceration", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 164-165 (1986).  |
|               | B59 | SKANBERG, et al., "Pharmacokinetics and Metabolism of Omeprazole in Animals", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 92-93. (1986).   |
|               | B60 | SMALLWOOD, et al., "Double-Blind Comparison of Omeprazole, 10 mg Versus 30 mg, for Healing Duodenal Ulcers", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 171-172 (1986).   |
|               | B61 | SOLVELL, Lennart, "Safety Aspects of Omeprazole", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 129-133 (1986).  |
|               | B62 | SUNDELL, et al., "Structure and Function of the Dog Gastric Mucosa During and After a 1-Year Treatment with Omeprazole. II. Effects on Gastric Acid Secretion and Blood Levels of Gastric Hormones", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 82-85 (1986).                           |
|               | B63 | SUNDLER, et al., "Inhibition of Gastric Acid Secretion by Omeprazole and Ranitidine. Effects on Plasma Gastrin and Gastric Histamine, Histidine Decarboxylase Activity and ECL Cell Density in Normal and Antrectomized Rats", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 39-45 (1986). |
|               | B64 | UUSITALO, et al., "Effect of Omeprazole on Ulcer Healing and Pentagastrin Stimulated Acid Secretion During and After Treatment in Patients with Duodenal Ulcer", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 139-140 (1986).   |
|               | B65 | WALAN, Anders, "Treatment of Duodenal Ulcer Disease. Clinical Results with Omeprazole", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 118-121 (1986).  |
|               | B66 | WALLMARK, et al., "The Relationship Between Gastric Acid Secretion and Gastric H <sup>+</sup> , K <sup>+</sup> -ATPase Activity", Journal of Biological Chemistry, Vol. 260, No. 25, pp. 13681-13684 (November 5, 1985).  |
|               | B67 | WALLMARK, Bjorn, "Mechanism of Action of Omeprazole", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 11-16 (1986).  |
|               | B68 | WALLMARK, et al., "Mechanism of Inhibition of H <sup>+</sup> -K <sup>+</sup> -ATPase by Omeprazole", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 59-60 (1986).   |
|               | B69 | WALLMARK, et al., "Mechanism of Action of Omeprazole", ISI Atlas of Science: Pharmacology, Vol. 1, pp. 158-161 (1987).  |
|               | B70 | WILSON, et al., "The Effect of Omeprazole on Acid and Pepsin Secretion in Duodenal Ulcer Patients", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 147-149 (1986).  |
| /CCI/         | B71 | YEOMANS, et al., "Morning or Evening Dosing with Low-Dose Omeprazole: Effects on 24-Hour Gastric Acidity Profiles in Duodenal Ulcer Patients", Scand. J.  |
| /Celia Chang/ |     | Date Considered 10/29/2008  |

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| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br>(Use as many sheets as necessary) |   | Application Number       | 10/797,374             |          |
|   |   | Filing Date              | 2004-3-10              |          |
|   |   | First Named Inventor     | Phillips, Jeffery O    |          |
|   |   | Art Unit                 | 1625                   |          |
|   |   | Examiner Name            | Chang, Celia C.        |          |
| Sheet   | 6 | 6                        | Attorney Docket Number | 04242350 |

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|------|-----|--|
|      |     | Gastroenterology, Vol. 21, Suppl. 118, pp. 152-153 (1986).   |
| /CC/ | B72 | Zegerid Product Information, February 2006.  |
|      | B73 | November 13, 2007 Detailed Statement of the Factual and Legal Bases from Par Pharmaceutical to Santarus, Inc. and The Curators of the University of Missouri.                        |
|      | B74 | December 6, 2007 Detailed Statement of the Factual and Legal Bases from Par Pharmaceutical to Santarus, Inc. and The Curators of the University of Missouri.                         |
|      | B75 | December 20, 2007 Complaint for Patent Infringement, Santarus, Inc. and The Curators of the University of Missouri v. Par Pharmaceutical with Exs. A-E, Case No. 07-827 (D. Del.).   |
|      | B76 | December 20, 2007 Report of the Filing or Determination of an Action Regarding a Patent or Trademark, Case No. 07-827-GMS (D. Del.).   |
|      | B77 | January 10, 2008 Answer Filed by Par Pharmaceutical, Case No. 07-827-GMS (D. Del.).  |
|      | B78 | June 16, 2008 Par's Objection and Responses to Curators of the University of Missouri's 1st Set of Requests for Production of Documents, Case No. 07-551-GMS (D. Del.).              |
|      | B79 | June 23, 2008 Responses and Objections of Tap Pharmaceutical Products Inc. to Defendant's Subpoena, Case Nos. 07-551-GMS and 07-827-GMS (D. Del.).                                   |
|      | B80 | June 26, 2008 Final Joint Claim Construction Chart, Case No. 07-551-GMS (D. Del.).   |
|      | B81 | July 9, 2008 Santarus' Responses to Par Pharmaceutical First Set of Interrogatories, Case No. 07-551-GMS (D. Del.).  |
|      | B82 | August 22, 2008 Defendant Par Pharmaceutical, Inc.'s Opening Claim Construction Brief Regarding U.S. Patent Nos. 6,489,346; 6,699,885; and 6,645,988, Case No. 07-551-GMS (D. Del.). |
|      | B83 | August 26, 2008 Plaintiff's Opening Claim Construction Brief, Case No. 07-551-GMS (D. Del.).   |
|      | B84 | September 22, 2008 Defendant's Answering Brief Regarding Claim Construction, Case No. 07-551-GMS (D. Del.).  |
|      | B85 | September 22, 2008 Declaration of Steven J. Fineman, Case No. 07-551-GMS (D. Del.).  |
| /CC/ | B86 | September 22, 2008 Plaintiff's Answering Brief Regarding Claim Construction, Case No. 07-551-GMS (D. Del.).  |

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| /Celia Chang/ | Date Considered | 10/29/2008 |
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